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Atty. Docket No.: 018547-046600US  
Client Ref. No.: 3242.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David Mack et al.

Application No.: 09/747,760

Filed: December 21, 2000

For: NOVEL COMPOSITIONS AND  
METHODS OF SCREENING FOR B  
CELL ACTIVITY MODULATIONS

Examiner: Padmashri Ponnaluri

Art Unit: 1627

RESPONSE TO RESTRICTION AND  
ELECTION OF SPECIES REQUIREMENT

#7  
AKD  
5-14-02

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicants provide the following response to the Office Communication  
dated February 26, 2002. A one month extension of time is submitted herewith as a  
separate paper:

Claims 1-21 are pending in the present application. The Examiner has  
requested that Applicants elect one group under 35 U.S.C. §121 as follows:

Group I        Claims 1-2, drawn to a method of screening a drug  
candidates comprising; providing a cell that expresses an expression profile gene,  
classified in class 435, subclass 6.

Group II        Claims 3-11, drawn to a method of screening drug  
candidates comprising providing a cell that expresses an expression profile gene set,  
classified in class 435, subclass 6.

Group III      Claims 12-15, drawn to a method of screening for a bioactive agent capable of binding to a B lymphocyte modulator protein (BLMP), classified in class 436, subclass 501.

Group IV      Claims 16-18, drawn to a method of evaluating the effect of an immunosuppressive drug (*in vivo*), classified in class 435, subclass 63.

Group V      Claims 19-21, drawn to an array of probes, classified in class 436, subclass 518 or class 536, subclass 23.1.

**I.      RESPONSE TO RESTRICTION REQUIREMENT**

**EXAMINING THE CLAIMS OF GROUPS I-II TOGETHER DOES NOT PLACE AN UNDUE EXAMINATION BURDEN ON THE EXAMINER**

In response to the Restriction Requirement dated February 26, 2002, Applicants elect to prosecute Group I, claims 1-2, drawn to a method of screening drug candidates comprising; providing a cell that expresses an expression profile gene.

The foregoing election is made with traverse, as Groups I and II set forth by the examiner stem from a common concept and theory, and are thus related. As such, prosecution of the claims of Groups I and II would not place a substantially greater burden on the examiner.

Restriction of an application is discretionary. A restriction requirement is made to avoid placing an undue examination burden on the Examiner and the Office. Where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. MPEP § 803.01. Applicants respectfully submit that examining the claims of Groups I and II together would not place and undue burden on the Examiner.

In establishing that an “undue burden” would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To

show undue burden resulting from searching difficulties, the Examiner must show one of the following, as set forth in MPEP § 808.02:

(1) *Separate classification thereof:*

This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(2) *A separate status in the art when they are classifiable together:*

Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(3) *A different field of search:*

Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.

In the present case, the examiner has indicated that Group I and II are both classified in the same class and subclass. Applicants submit that searching Groups I and II places no undue examination burden on the Examiner. In particular, the claims corresponding to method of screening drug candidates (Claims 1-11) should be examined together, without restricting the claims into two individual groups. Applicants therefore respectfully request that Groups I and II be joined together as one group and examined accordingly.

## II. RESPONSE TO ELECTION OF SPECIES REQUIREMENT

### THE DIFFERENT SPECIES OF GROUP II ARE NOT MUTUALLY EXCLUSIVE

The examiner also stated that the instant application contains claims directed to the following patentably distinct species:

- (a) if Group I is elected, Applicants were requested to elect a single species of cell.
- (b) if Group II is elected, Applicants were requested to elect one type of set from the following:
  - i) set comprises tolerance set;
  - ii) set comprises stimulation set; and if stimulation set is elected, Applicants were further requested to elect a gene in which the expression is increased; and a gene in which the expression is decreased;
  - iii) set comprises immunosuppression set; and if immunosuppression set is elected, Applicants were further requested to elect a gene in which the expression is increased; and a gene in which the expression is decreased;
- (c) if Group IV is elected, Applicants were requested to elect a single gene;
- (d) if Group V is elected, Applicants were requested to elect a single gene.

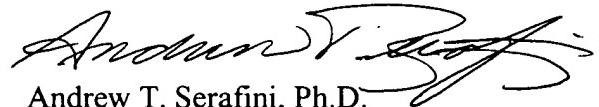
Applicants elect B cells as the single species for Group I. Applicants elect the tolerance set as the single species for Group II, with traverse.

The election of species requirement for Group II is respectfully traversed on the basis that although the designated species in a particular group may be patentably distinct, they are not mutually exclusive. MPEP 806.04(f) specifies that “[c]laims to be restricted to different species must be mutually exclusive.” The examiner has not stated which of the indicated species is mutually exclusive to the claimed expression profile gene set. Because the election of species requirement requires election between nonmutually exclusive species, it is submitted that it should be withdrawn.

**CONCLUSION**

Applicants request that the application now be examined on the merits. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400, ext. 5228.

Respectfully submitted,



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